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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,456	01/28/2002	Pascale Pouzet	I/1168	4239

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EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,456

Applicant(s)

POUZET ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-18 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-18 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 11-18 and 21-28 are currently pending in the instant application. Claims 9-10, 19-20 and 29-30 were cancelled in the amendment filed 7 February 2003 and claims 1-3, 7, 8 and 21-28 were amended. The 35 U.S.C. 103 rejection of claims 1-8, 11-18 and 21-28 is maintained.

Response to Amendment

Applicant's amendment filed 7 February 2003 has been entered into the case as Paper No. 9. Applicants cancellation of claims 9-10, 19-20 and 29-30 has made the objection to the claims as being substantial duplicates moot. Applicants amendment of claims 7, 8 and 21-28 has overcome the 35 U.S.C. 112 rejection of these claims.

103 Rejection Maintained

The rejection of claims 1-8, 11-18 and 21-28 under 35 U.S.C. 103(a) as being unpatentable over WO 96/32939 and DE 3712385 is MAINTAINED for the reasons set forth in the Office Action mailed 26 August 2002, Paper No. 6 and for the reasons as found below in the response to applicants arguments. This rejection might be overcome by submitting a 37 C.F.R. 1.132 declaration showing the unobvious and unexpected superiority of the selective activity on the bladder without substantially affecting the cardiac circulatory system and the unexpected superiority in regards to bioavailability and metabolism over the compounds as found in WO 96/32939 and DE 3712385.

Response to Arguments

In regards to the 35 U.S.C. 103 rejection, applicant's arguments filed 7 February 2003 have been fully considered but they are not persuasive. Applicant argues that the

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examiner has failed to establish a *prima facie* case of obviousness by failing to satisfy the three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. However, this argument is not found persuasive for essentially the same reasons as those found in the 35 U.S.C. 103 rejection found in Paper No. 6. WO 96/32939 discloses phenyliminoimidazolidine tautomeric equivalent derivatives of the formula Ib and II (page 2 and page 3) with preferences towards compounds substituted with hydrogen, bromine and chlorine at positions R1, R2, R3 and R5 and alkyl at position R4 (page 4 and page 5) which are useful for the treatment of urinary incontinence. Examples of alkyl as isopropyl and tertiary butyl are found on page 6, lines 13-18. DE 3712385 discloses phenyliminoimidazolidine derivatives of the formula I, page 2, which are useful as an alpha1-adrenergic agonist, page 4, and discloses a positional isomer of the compounds as instantly claimed (page 2, line 42). These references provide a suggestion or motivation to combine the reference teachings since they both disclose phenyliminoimidazolidine derivatives that are useful for the treatment of urinary incontinence or as alpha1-adrenergic agonists. The reasonable expectation of success comes from WO 96/32939 generically encompassing that as instantly claimed and providing preferences for the substituents towards that which is instantly claimed which are useful for the treatment of urinary incontinence and from DE 3712385 disclosing a positional isomer of the compounds as

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instantly claimed, which is useful as an alpha1-adrenergic agonist. As can be seen from above and from the previous office action mailed 26 August, 2002 (Paper No. 6) the references teach and suggest all of the claim limitations.

Applicant also argues that applicant has pointed out some advantages of the compounds of the claimed invention on page 3 of the specification. However, this argument is not found persuasive because it is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a)-(g). The stated advantages on page 3 of the specification are not necessarily unexpected results and are also not a claim limitation. Furthermore, the unexpected results should be demonstrated with evidence that the difference in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonable commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, the paragraph on page 3 of the specification has been considered but not found persuasive because there is no data provided to demonstrate the unexpected results, i.e. there is no comparison data between the instantly claimed compounds and the closest prior art in regards to the selective activity on the bladder without substantially affecting the cardiac circulatory system, nor is there any data demonstrating the unexpected results of the favorable properties with regard to bioavailability and metabolism, i.e. there is no comparison data

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provided to demonstrate the unexpected superiority in regards to bioavailability and metabolism.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

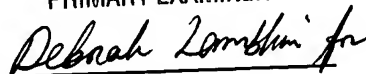
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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